

### **III. Remarks**

#### **A. Status of the Application**

Claims 53-72 are pending. Claims 26-30 and 33-35 that were previously pending are canceled by the present paper without prejudice to or disclaimer of the subject matter therein. New claims 53-72 are submitted by the present paper. Reconsideration of this application in light of the following remarks is respectfully requested.

#### **B. Claim Rejections – 35 U.S.C. §103**

All of the previously pending claims 26-30 and 33-35 were rejected under 35 U.S.C. §103(a) as being unpatentable over various combinations of U.S. Patent No. 5,658,286 to Sava (“the Sava patent”), U.S. Patent No. 5,397,363 to Gelbard (“the Gelbard patent”), U.S. Patent No. 4,743,260 to Burton (“the Burton patent”), U.S. Patent No. 6,336,930 to Stalcup et al. (“the Stalcup patent”), U.S. Patent No. 6,607,530 to Carl et al. (“the Carl patent”), and U.S. Patent No. 5,415,661 to Holmes (“the Holmes patent”). As all of the previously pending claims have been canceled, these rejections are moot and will not be addressed at this time. However, Applicants will generally address these references below in the context of new claims 53-72.

#### **C. New Claims**

New claims 53-72 are added by the present paper and recite combinations of limitations not disclosed or suggested by the cited references. For example, new independent claim 53 requires:

53. A prosthetic stabilization system for subcutaneous assembly within a patient's body, the system comprising:  
a first pair of bone anchors, each comprising a distal portion and a proximal portion, the proximal portion having a portal extending therethrough;  
a second pair of bone anchors, each comprising a distal portion and a proximal portion, the proximal portion having a portal extending therethrough;  
a first elongated support structure, sized to extend between a first vertebra and a second vertebra and through the portals in the first pair of bone anchors;  
a second elongated support structure, sized to extend between the first vertebra and the second vertebra and through the portals in the second pair of bone anchors; and

an inflatable crossbar extending between the first and second elongated support structures, the crossbar having a deflated insertion configuration and an inflated fixation configuration such that in the inflated fixation configuration the first and second support structures and the crossbar are connected to form an orthopedic fixation structure for supporting at least the first and second vertebrae.

First, it is clear that the flexible tubing 18 of the Sava patent cannot meet the recited limitations of the cross bar of claim 26. First, the flexible tubing 18 of the Sava patent does not appear to be inflatable as required. The flexible tubing 18 is not inflated by the fluid molding material 28. Rather, the flexible tubing 18 maintains has the same profile both prior to receiving the fluid molding material 28 and after introduction of the fluid molding material. The fluid molding material 28 is injected into the flexible tubing 18 without changing the shape, size, or volume of the tubing. So, while the fluid molding material 28 is injected into the flexible tubing 18 there is no inflation of the tubing. This is consistent with the fact that the tubing of the Sava patent is utilized as a template for forming a spinal support bar, where the shape of the tubing serves as the basis or template for shaping the metal bar. Thus, the flexible tubing 18 also cannot meet the limitation that “in the inflated fixation configuration the first and second support structures and the crossbar are connected to form an orthopedic fixation structure for supporting at least the first and second vertebrae.” In that regard, the tubing 18 is filled with a quick-setting molding material to form “a rigid **temporary master** (Fig. 2C) that is **used as a template** to form the element.” Col. 5, ll. 43-67 (emphasis added). The tubing 18 with the quick-setting molding is not utilized as a spinal support bar. Instead the tubing 18 is simply used as a template for shaping the actual metal spinal support bars that are implanted into the patient. Col. 5, ll. 59-62. One skilled in the art simply would not use a temporary template for forming a bone fixation element in place of an actual bone fixation element. Thus, for at least these reasons the cited references do not disclose all of the recited elements of new independent claim 53. New claims 54-62 depend from and further limit claim 53 and recite additional limitations not disclosed or suggested by the cited references.

Similarly, 63-72 recite combinations of limitations not disclosed or suggested by the cited references. For example, new independent claim 63 recites:

63. A prosthetic stabilization system for subcutaneous assembly within a patient's body, the system comprising:

a first spinal stabilization member comprising an inflatable balloon with a proximal end portion, a distal end portion, and a flexible wall defining an interior cavity extending between the proximal and distal end portions, the first stabilization member sized to extend between a first vertebra and a second vertebra;

a second spinal stabilization member comprising an inflatable balloon with a proximal end portion, a distal end portion, and a flexible wall defining an interior cavity extending between the proximal and distal end portions, the second stabilization member sized to extend between the first and second vertebrae;

a crossbar attachable to the first and second spinal stabilization members, the crossbar comprising an inflatable balloon with a proximal end portion, a distal end portion, and a flexible wall defining an interior cavity extending between the proximal and distal end portions, the crossbar having a first deflated state with a first diameter and a second inflated state with a second diameter, the second diameter being greater than the first diameter;

a first connector for attaching the crossbar to the first stabilization member, the first connector comprising a first aperture having a third diameter for receiving the crossbar and a second aperture having a fourth diameter for receiving the first stabilization member, wherein the third diameter of the first aperture is less than the second diameter of the crossbar; and

a second connector for attaching the crossbar to the second stabilization member, the second connector comprising a third aperture having a fifth diameter for receiving the crossbar and a fourth aperture having a sixth diameter for receiving the second stabilization member, wherein the fifth diameter of the third aperture is less than the second diameter of the crossbar;

wherein the inflatable crossbar is elongated to extend through the first aperture of the first connector and the third aperture of the third connector in its first deflated state such that inflation of the crossbar to the second inflated state while extending through the first and third apertures secures the crossbar to the first and second connectors.

Claims 64-68 depend from and further limit claim 63. Further, new independent claim 69 recites:

69. An apparatus for stabilizing vertebrae, comprising:  
a first elongated support structure sized to extend between a first vertebra and a second vertebra;  
a second elongated support structure sized to extend between the first vertebra and the second vertebra; and  
an inflatable crossbar for connecting the first and second support structures, the crossbar having a deflated insertion

configuration and an inflated fixation configuration and including an opening for receiving a hardenable media for inflating the cross bar from the deflated configuration to the inflated configuration such that in the inflated fixation configuration the crossbar and the first and second support structures are connected to form an orthopedic fixation structure for stabilizing at least the first and second vertebrae.

Claims 70-72 depend from and further limit claim 69. Accordingly, Applicants believe all of the pending claims 53-72 are patentable over the cited references.

**IV. Conclusion**

It is believed that all matters set forth in the Final Office Action mailed October 10, 2008 have been addressed and that all of the pending claims are in condition for allowance. An indication of allowance of the pending claims is respectfully requested.

Should the Examiner deem that an interview with Applicant's undersigned attorney would expedite consideration of this application, the Examiner is invited to call the undersigned attorney at the telephone number indicated below.

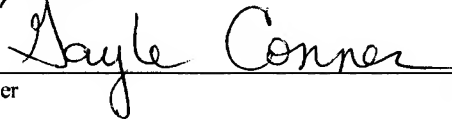
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